

Claims

*Sub A*

1. A controlled drug release system for retinoic acid which comprises microsphere in which biodegradable polymer and amphoteric block copolymer are mixed and retinoic acid incorporated into the microsphere.
2. The drug release system for retinoic acid according to Claim 1, wherein the retinoic acid is selected from the group consisting of all-trans-retinoic acid, 13-cis-retinoic acid, 9-cis-retinoic acid, other retinoids and the mixture thereof.
3. The drug release system for retinoic acid according to Claim 1, wherein the biodegradable polymer is selected from the group consisting of natural polymer, synthetic polymer and the mixture thereof.
4. The drug release system for retinoic acid according to Claim 1, wherein the amphoteric block copolymer is di-, tri- or multi-block copolymer or graft copolymer of the biodegradable polymer according to claim 3 and polyethylene glycol.
5. The drug release system for retinoic acid according to Claim 1 or 5, wherein the mixing ratio of the biodegradable polymer and the amphoteric block copolymer is 1:0~100 part by weight.
6. The drug release system for retinoic acid according to Claim 1, wherein the mixing ratio of retinoic acid and microsphere is between 0.1 ~ 50 wt% based on the weight of microsphere.
7. The drug release system for retinoic acid according to Claim 1, wherein

*Sub A*

the particle size of the microsphere is between 0.001 and 1000  $\mu\text{m}$ .

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8. The drug release system for retinoic acid according to Claim 1 or 5, wherein the amphoteric block copolymer comprises 2 ~ 8 wt% of DiPLE or up to 20 wt% of TriPLE based on the total weight of the release system.

9. The drug release system for retinoic acid according to any of Claims 1 to 8 for use in the prevention or treatment of patients suffering from the diseases selected from the group consisting of acute promyelocytic leukemia, head and neck cancer, skin cancer, lung cancer, breast cancer, cervical cancer, bladder cancer, and acute promyelocytic leukemia.

10. A method of treating patients in need of retinoic acid administration, said method comprising the oral administration of the drug release system according to any of Claims 1 to 9 into the patients.

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